

CLAIMS

What is claimed is:

1. A method of treating a condition characterized by increased expression or activity of laminin 5, the method comprising administering to a subject in need an effective amount of an agent that affects processing of laminin 5 by a BMP-1 related protein.
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2. A method of treating cancer, the method comprising administering to a subject in need of an effective amount of an agent that affects processing of laminin 5 by a BMP-1 related protein.
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3. A method of treating glioma, the method comprising administering to a subject in need an effective amount of an agent that affects processing of laminin 5 by a BMP-1 related protein.
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4. A method of treating a condition characterized by a neoplastic epithelial cells, the method comprising administering to a subject in need an effective amount of an agent that affects processing of laminin 5 by a BMP-1 related protein.
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(Art A)
5. The method of claim 4, wherein the epithelial cells are selected from the group consisting of squamous cells, keratinocytes, mucosal epithelial cells, gastrointestinal epithelial cells, corneal epithelia of the eye, and epithelial cells of the urinary and reproductive tract.
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6. A method of treating squamous cell carcinoma, the method comprising administering to a subject in need an effective amount of an agent that affects processing of laminin 5 by a BMP-1 related protein.

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- Rule A2*
7. The method of claim 6, wherein the squamous cell carcinoma is selected from the group consisting of skin cancer, lung cancer, head cancer, neck cancer, oral cancer, cervical cancer, tongue cancer, gastric cancer, colorectal, throat cancer, cancer of the urinary tract, cancer of the reproductive tract, esophageal cancer, throat cancer, and bronchiogenic carcinoma.

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8. The method of claim 6, wherein the agent affects processing of the $\alpha 3$ chain of laminin 5.

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9. The method of claim 6, wherein the agent affects processing of the $\gamma 2$ chain of laminin 5.

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10. The method of claim 6, wherein the agent affects processing of laminin 5 by BMP-1.

11. The method of claim 6, wherein the agent affects processing of laminin 5 by mTld.

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12. The method of claim 6, wherein the agent affects processing of laminin 5 by mTll-1.

13. The method of claim 6, wherein the agent affects processing of laminin 5 by mTll-2.

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14. The method of claim 6, wherein the agent additionally confers an anti-scarring effect.

- 5 15. A composition for the treatment of a condition associated with increased expression or activity of laminin 5, the composition comprising an agent that affects processing of laminin 5 by a BMP-1 related protein and an acceptable carrier.
- 10 16. A composition for the treatment of squamous cell carcinoma, the composition comprising an agent that affects processing of laminin 5 by a BMP-1 related protein and an acceptable carrier.
- 15 17. The composition of claim 16, wherein the agent affects at least one protein selected from the group consisting of BMP-1, mTld, mTll-1, and mTll-2.
- 20 18. A method of diagnosing the presence of a condition characterized by increased expression or activity of laminin 5 in a subject, the method comprising:
- (a) obtaining a sample;
- (b) detecting the level of expression or activity of a BMP-1 related protein in the sample;
- (c) comparing the level of expression or activity of the BMP-1 related protein in the sample to a standard level of expression or activity of the BMP-1 related protein.
- 25 19. A method of diagnosing the presence of squamous cell carcinoma in a subject, the method comprising:
- (a) obtaining a sample;
- (b) detecting the level of expression of a BMP-1 related protein in the sample;

- 5 (c) comparing the level of expression or activity of the BMP-1 related protein to a standard level of expression or activity of the BMP-1 related protein.
- 10 20. The method of claim 19, wherein the BMP-1 related protein is selected from the group consisting of BMP-1, mTld, mTll-1, and mTll-2.
- 15 21. The method of claim 19, wherein the sample is a tissue sample.
- 20 22. The method of claim 19, wherein the sample is a urine sample.
- 25 23. The method of claim 19, wherein the sample is a serum sample.
- 30 24. The method of claim 19, wherein the sample is a blood sample.
25. A diagnostic kit for use in diagnosing the presence of a condition associated with increased expression or activity of laminin 5 in a sample from a subject, the kit comprising:
- 15 (a) an anti-BMP-1 antibody reactive with BMP-1 related proteins; and
- 20 (b) a labeled reagent capable of forming a complex with a BMP-1 related protein or with the anti-BMP-1 antibody.
26. A method of screening for an agent that affects the processing of laminin 5 by BMP-1 related proteins, the method comprising:
- 30 (a) contacting a sample containing unprocessed laminin 5 with at least one BMP related protein and the agent;
- 25 (b) measuring the level of processed laminin 5 in the sample;
- 30 (c) measuring the level of processed laminin 5 in a control sample; and

5 (d) comparing the level of processed laminin 5 in the sample with
the level of processed laminin 5 in the control sample.

27. An isolated polypeptide comprising a BMP-1 cleavage sequence, the
polypeptide comprising the amino acid sequence of SEQ ID NO:1.

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28. An isolated polynucleotide encoding the polypeptide of claim 27.

29. An isolated polynucleotide that is complementary to the polynucleotide
of claim 28.

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30. An antibody that binds to the polypeptide of claim 27.

31. A method of screening for an agent that affects the processing of
laminin 5 by BMP-1 related proteins, the method comprising:

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(a) contacting a sample containing at least one polypeptide
comprising SEQ ID NO:1 with a BMP-1 related protein and an
agent;

(b) measuring the level of the polypeptide that is processed;

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(c) measuring the level of the polypeptide that is processed in a
control sample; and

(d) comparing the level of the polypeptide that is processed in the
sample to the level of polypeptide that is processed in the
control sample.

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32. An isolated polypeptide comprising a BMP-1 cleavage sequence, the
polypeptide comprising the amino acid sequence of SEQ ID NO:2.

- 5 33. An isolated polypeptide comprising a BMP-1 cleavage sequence, the polypeptide comprising the amino acid sequence of SEQ ID NO:3.
- 10 34. An isolated polypeptide comprising a BMP-1 cleavage sequence, the polypeptide comprising the amino acid sequence of SEQ ID NO:4.
- 15 35. An isolated polypeptide comprising a BMP-1 cleavage sequence, the polypeptide comprising the amino acid sequence of SEQ ID NO:5.
36. A method of affecting laminin 5 expression or activity, the method comprising contacting laminin 5 with an effective amount of an agent that affects processing of laminin 5 by a BMP-1 related protein.

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